

REMARKS

Claims 12-14 are pending. Claims 12-14 have been amended. Claim 15 has been added. No new matter has been added. Upon entry of these amendments, claims 12-15 will be pending.

The specification is objected to because the information relating to the government contract number on page 1 of the specification is blank. The specification has been amended to remove the blank. If the undersigned representative becomes aware of any relevant government contracts, the specification will be amended to include those government contract numbers. Accordingly, it is respectfully requested that the objection be withdrawn.

Claims 12-14 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Claims 12-14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lai *et al.* (Biochimica et Biophysica Acta, Vol. 1517, Pages 449-454, 2001) (hereinafter “Lai”) in view of Benson *et al.* (Nucleic Acids Research, Vol. 21, Pages 2963-2965, 1993) (hereinafter “Benson”).

Rejection of Claims 12-14 under 35 U.S.C. § 101

Claims 12-14 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. This rejection is respectfully traversed.

On page 4 of the Office Action, the Examiner asserts that the “instant claims do not recite or inherently involve any transformation of an article, therefore the Examiner must determine if the instant claims have a tie to a particular machine or apparatus. Instant claims 12 and 14 do not recite any limitation that ties the recited abstract process to any particular machine or apparatus and, thus, are not statutory.” With regard to claim 13, the Examiner asserts that “Claim 13 does recite generic computer readable media and module for performing the abstract/computational steps as set forth in the claimed process, however said generic components reads only on a general apparatus that would preempt said abstract/computational process.” Accordingly, claims 12-14 have been amended to recite how the claims are tied to a particular machine or apparatus. Therefore, it is respectfully requested that the rejection of claims 12-14 under 35 U.S.C. § 101 be withdrawn.

Rejection of Claims 12-14 under 35 U.S.C. § 103(a)

Claims 12-14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lai in view of Benson. This rejection is respectfully traversed.

Lai and Benson describe the use of BLAST searching and a GenBank sequence database. Lai recites “A TBLASTN program was used for sequence similarity analysis...A previously described Java-written computer program was modified to extract protein sequences from the original *Drosophila* data set, perform TBLASTN searches against the HGI database on our local server, and extract information from BLAST reports for subsequent analysis.” Page 449, col. 2. Benson recites that “The retrieval system allows for traditional keyword searching and uses pre-computed statistical measures of relatedness to allow queries that will find all articles or sequences similar to an article or sequence of interest.” Page 2963, col. 2. However, the undersigned representative does not contest the patentability of the pending claims in view of BLAST searches or genetic sequence databases. Indeed, the Background of the pending application recites:

As noted by the National Center for Biotechnology Information (NCBI), ***BLAST***® (***Basic Local Alignment Search Tool***) is a set of similarity search programs designed to explore genetic sequence databases available through NCBI. The BLAST programs have been designed for speed, with a minimal sacrifice of sensitivity to distant sequence relationships. The scores assigned in a BLAST search have a well-defined statistical interpretation, making real matches easier to distinguish from random background hits. BLAST uses a heuristic algorithm that seeks local as opposed to global alignments and is therefore able to detect relationships among sequences that share only isolated regions of similarity. The Expected Value (“*E*”) as noted in BLAST search results is a parameter that describes the number of hits of the type shown that one can expect to see just by chance when searching a database of a particular size. It decreases exponentially with the Score (“*S*”) that is assigned to a match between two sequences. *E* can be interpreted as the random background noise that exists for matches between sequences. For example, an *E* value of 1 assigned to a hit can be interpreted as meaning that in a database of the current size, one might expect to see one match with a similar score simply by chance. This can be interpreted to mean that the lower the *E*-value, or the closer it is to “0”, the more significant the match is.

Para. [0007] (emphasis added). Further, the pending application recites that “a subset of the genomic data 105 of the organism under investigation is obtained. The subset 105 can be obtained from known genomic data source 10, e.g., UniGene, ***GENBANK***® genomic data

source, European Molecular Biological Laboratory (EMBL), among other sources.” Para. [0042] (emphasis added). BLAST and GenBank are used in Lai and Benson to find sequences that resemble the query sequence. BLAST looks for similarities between molecules and ranks the molecules based on these similarities. A search can be run using user-defined parameters, and the system outputs a list of results with percent identities to the query sequence.

In contrast, amended claim 12 recites “searching a selected genomic computer database using the query-length sequence and the similarity search engine for those sequences having homology above a threshold with at least one set of organisms other than the set under investigation” and “parsing results of the search for a sequence unique to the selected genomic database.” Similarly, claim 13 recites “operable to parse results of the search for those sequences having homology above a threshold with at least one set of organisms other than the set under investigation and otherwise unique within the selected genomic database,” and claim 14 recites “parsing results of the search for those sequences, other than sequences of the second set, having homology above a threshold with the second set and otherwise unique within the selected genomic database.” Here, the search identifies similar sequences and removes those sequences, so that the remaining sequences are unique. Dependent claim 15 has been added and is also directed to this feature.

Lai and Benson do not teach or suggest parsing the results of a search for those sequences showing uniqueness to the set. As described in the pending application:

Bioinformatic tools such as BLAST, are intended to identify similarities between sequences. *While similarities between the sequences of organisms are useful in some types of analysis, the differences between genomes can be useful in the identification and characterization of microorganisms. Unfortunately, bacterial and fungal genomes are so large that it is resource-intensive to subtract common sequences in order to identify unique sequences from all known genomes.* Frequently only small fragments of genomic sequences have been identified as unique are available for identification of an organism. The increasing number of genomes that have been, or will soon be, sequenced is one incentive for identifying large fragments of known genomes.

Para. [0034] (emphasis added). Lai and Benson merely search a database to determine a similarity of a sequence to a sequence in the database. In claim 12, however, the search results are then parsed for a sequence unique to the selected genomic database. Lai and Benson fail to teach or suggest parsing the search results for a unique sequence.

In the Response to Arguments on page 10 of the Office Action, the Examiner asserts that Lai's thresholds can be used to show uniqueness in the same way that the threshold can show similarity. However, although Lai determines similarity using these thresholds, Lai does not parse the similarity search results to determine a unique sequence. The pending application recites "Preferred embodiments parse 130 the similarity search program output 125 to identify sequences lacking significant similarity with other organisms in the selected database, e.g., unique genomic sequences 132." Para. [0050]. As a result, the search program is used to determine similar sequences, but then those similar sequences are parsed to identify unique sequences. Searching for unique sequences by varying the threshold does not perform the same function as described in the pending claims. The result of such a search would be a list of highly similar sequences. In contrast, in the pending claims, the similar sequences are parsed to find unique sequences.

Thus, Lai and Benson do not teach or suggest each and every element of claims 12-15. Accordingly, it is respectfully requested that the rejection of claims 12-14 under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

The undersigned representative respectfully submits that this application is in condition for allowance, and such disposition is earnestly solicited. If the Examiner believes that the prosecution might be advanced by discussing the application with the undersigned representative, in person or over the telephone, we welcome the opportunity to do so. In addition, if any additional fees are required in connection with the filing of this response, the Commissioner is hereby authorized to charge the same to Deposit Account No. 50-4402.

Respectfully submitted,

Date: February 6, 2009
KING & SPALDING LLP
1700 Pennsylvania Avenue, N.W.
Washington, D.C. 20006-4706
(202) 626-8980

By: /Eric Sophir Reg. No. 48,499/
Eric L. Sophir
Registration No. 48,499